JUN 1 9 2001

K011634

510(k) Summary of Safety and Effectiveness
ArthroCare Corporation
ENTec® ReFlex™ Wand, ArthroCare® System 2000, ENTec® Surgery System , ArthroCare® Orthopedic Surgery System, ArthroCare® Electrosurgery System, Visage® Cosmetic Surgery System, and ArthroCare® Bipolar Loop (Electrosurgery Systems)

General Information

Manufacturer:
ArthroCare, Corporation
595 North Pastoria Avenue
Sunnyvale, CA 94085-2936

Establishment Registration Number: 2951580

Contact Person:
Bruce Prothro
Vice President, Regulatory Affairs, Quality Assurance, and Clinical Research

Date Prepared: May 25, 2001

Device Description

Classification Name:
Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400)

Trade Name:
ENTec® ReFlex Wand
ArthroCare® System 2000
ENTec® Surgery System
ArthroCare® Orthopedic Electrosurgery System
ArthroCare® Electrosurgery System
Visage® Cosmetic Surgery System
ArthroCare® Bipolar Loop

Generic/Common Name: Electrosurgical Device and Accessories

Predicate Devices

- ENTec ReFlex Wand — K000778
- ArthroCare System 2000 — K001588
- ENTec Surgery System, ArthroCare Orthopedic Electrosurgery System, and ArthroCare Electrosurgery System — K001936
- Visage Cosmetic Surgery System — K003624
- ArthroCare Bipolar Loop — K010568

Intended Uses

- The ENTec ReFlex Wand is indicated for ablation and coagulation of soft tissue in otolaryngological (ENT) procedures, including the treatment of snoring, nasal airway obstruction by reduction of hypertrophic nasal turbinates, and submucosal tissue shrinkage.

- The ArthroCare System 2000 is indicated for resection, ablation, and coagulation of soft tissues and hemostasis of blood vessels in orthopedic, arthroscopic, spinal, and neurosurgical procedures.

- The ENTec Surgery System is intended for ablation and coagulation of soft tissue in otorhinolaryngology (ENT) surgery including head, neck, oral, and sinus surgery.

- The ArthroCare Orthopedic Electrosurgery System is indicated for resection, ablation, and coagulation of soft tissues and hemostasis of blood vessels in orthopedic, arthroscopic, and spinal procedures.

- The ArthroCare Electrosurgery System is indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in general, plastic, and reconstructive surgery. It is intended to be used in procedures using conductive solutions, such as normal saline.

- The Visage Cosmetic Surgery System is a bipolar electrosurgical device intended for general dermatologic surgery that may include skin resurfacing for the treatment of wrinkles, rhytids, and furrows, as well as soft tissue resection/removal and hemostasis/coagulation. It is intended to be used in procedures using conductive solutions such as normal saline.

- The ArthroCare Bipolar Loop is indicated for resection, ablation, and excision, as well as hemostasis of blood vessels in patients requiring endoscopic surgery for general urological procedures including transurethral prostatectomy (TURP), transurethral incisions in the prostate (TUIP), and non-malignant tumors of the bladder wall.

Product Description

The ArthroCare Electrosurgery Systems are bipolar, high frequency electrosurgical Systems consisting of three components: an electrosurgical generator called the System 2000 Controller, a disposable bipolar single use Wand designed for specific indications, and the reusable patient Cable.

Substantial Equivalence

This Special 510(k) proposes a modification in materials to the Wand component of the Electrosurgery Systems, which were previously cleared in K000778 (May 3, 2000), K001588 (August 17, 2000), K001936 (July 19, 2000), K003624 (December 20, 2000), and K010568 (March 27, 2001). The technology, principle of operation, intended uses, performance specifications, dimensional specifications, labeling, packaging, and sterilization parameters of the Electrosurgery Systems remain the same as in the previously cleared 510(k)s.

Summary of Safety and Effectiveness

The modified Wand component of the Electrosurgery Systems, as described in this submission, is substantially equivalent to the predicate Wands. The proposed modification in materials is not a substantial change or modification, and does not significantly affect the safety or efficacy of the devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 9 2001

Mr. Bruce Prothro
Vice President, Regulatory Affairs,
Quality Assurance and Clinical Research
ArthroCare Corporation
595 North Pastoria Avenue
Sunnyvale, California 94085

Re: K011634
Trade/Device Name: ENTec® ReFlex Wand
ArthroCare® System 2000
ENTec® Surgery System
ArthroCare® Orthopedic Electrosurgery System
ArthroCare® Electrosurgery System
Visage® Cosmetic Surgery System
ArthroCare® Bipolar Loop
Regulation Number: 878.4400
Regulatory Class: II
Product Code: GEI
Dated: May 25, 2001
Received: May 29, 2001

Dear Mr. Prothro:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to

comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications Statement

Device Names: ENTec® ReFlex™ Wand
ArthroCare® System 2000
ENTec® Surgery System
ArthroCare® Orthopedic Electrosurgery System
ArthroCare® Electrosurgery System
Visage® Cosmetic Surgery System
ArthroCare® Bipolar Loop

510(k) Number: K011634

Indications for use:

- The ENTec ReFlex Wand is indicated for ablation and coagulation of soft tissue in otolaryngological (ENT) procedures, including the treatment of snoring, nasal airway obstruction by reduction of hypertrophic nasal turbinates, and submucosal tissue shrinkage.

- The ArthroCare System 2000 is indicated for resection, ablation, and coagulation of soft tissues and hemostasis of blood vessels in orthopedic, arthroscopic, spinal, and neurosurgical procedures.

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- The ArthroCare Electrosurgery System is indicated for resection, ablation, and coagulation of soft tissue and hemostasis of blood vessels in general, plastic, and reconstructive surgery. It is intended to be used in procedures using conductive solutions, such as normal saline.

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- The ArthroCare Bipolar Loop is indicated for resection, ablation, and excision, as well as hemostasis of blood vessels in patients requiring endoscopic surgery for general urological procedures including transurethral prostatectomy (TURP), transurethral incisions in the prostate (TUIP), and non-malignant tumors of the bladder wall.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109) X OR Over-the-Counter Use ____

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011634